

State of California—Health and Human Services Agency
Department of Health Services



ARNOLD SCHWARZENEGGER
Governor

June 14, 2005

TO: California Vaccines for Children (VFC) Program Providers

FROM: Robert Schechter, M.D., F.A.A.P., Chief
Technical Assistance Section
Immunization Branch

Howard Backer, M.D., M.P.H., Chief
Immunization Branch

SUBJECT: MENINGOCOCCAL CONJUGATE VACCINE INCORPORATED INTO THE VFC
PROGRAM

In January 2005, U.S. Food and Drug Administration (FDA) licensed a quadrivalent meningococcal conjugate vaccine (MCV4) FDA for use in persons aged 11-55 years old. In February, MCV4 was added to the Vaccines for Children Program (http://www.cdc.gov/nip/vfc/acip_vfc_resolutions.htm). This letter summarizes information about use of MCV4 in the VFC program.

Background and Composition

In comparison to polysaccharide vaccines, conjugate vaccines have proven to be extremely effective in providing sustained protection against *Haemophilus influenzae* type B and the pneumococcus. Since their introduction in 1999, monovalent Group C meningococcal conjugate vaccines have greatly reduced the incidence of Group C meningococcal disease in England. Several Canadian provinces have used monovalent Group C meningococcal conjugate vaccines since 2001. The incidence of meningococcal disease is highest during infancy with a secondary peak in fatal disease during late adolescence and early adulthood.

MCV4 is made of meningococcal capsular polysaccharide antigens conjugated to diphtheria toxoid protein. MCV4 prevents invasive meningococcal disease caused by four common serogroups of *Neisseria meningitidis*, A, C, Y and W-135. MCV4 offers no protection against meningococcal serogroup B, cause of most meningococcal cases during infancy and over 40% of all cases in California, or against diphtheria.

How to order

VFC Providers may order MCV4 using the attached revised order form (DHS 8501 (5/05)). Remember to complete all the boxes in the four columns of the order form, even if you are ordering only MCV4. Maintain a copy of your order forms for your office files. Please be aware that your orders of MCV4 may be adjusted, especially during this introductory phase.

Eligible Groups for receipt of VFC Supplies of MCV4

VFC supplies of MCV4 may be given to VFC-eligible children and adolescents age 11-18 years old.

If available supplies of MCV4 are limited, as is possible in 2005 and 2006, priority should be given to the following groups:

- Children and adolescents aged 11-18 years old who are:
 - Travelers to countries in which *N. meningitidis* is hyperendemic or epidemic, particularly if contact with the local population will be prolonged;
 - Entering or current college freshmen who will reside in dormitories;
 - Persons with terminal complement deficiencies and those with anatomic or functional asplenia; or
 - Infected with HIV
- Children aged 11-12 years old at their preadolescent health assessment visit
- Adolescents at high-school entry (approximately 15 years old) who were not vaccinated at the preadolescent visit

Dosing Schedule

MCV4 is given as a single dose of 0.5 ml. administered intramuscularly (IM), preferably in the deltoid region and never in the buttocks. As with other IM injections for patients aged 11 years and older, use a 25-gauge needle that is at least a 1 inch in length. Protective levels of antibody are usually achieved within 7-10 days after vaccination.

Revaccination with MCV4 may be considered within three to five years after vaccination with either polysaccharide or conjugate meningococcal vaccine for those who remain at high risk of meningococcal disease due to travel to hyperendemic or epidemic areas, terminal complement deficiency, anatomic or functional asplenia, or infection with HIV. More data will become available in following years to refine recommendations on revaccination for persons who were previously vaccinated with MCV4.

Administration with other vaccines

MCV4 may be given at the same time as other vaccines in separate sites. Of the vaccines used routinely in the US, only the concomitant administration of Td has been studied in detail; the safety and immunogenic of both Td and MCV4 are not affected when given at the same time.

Potential Vaccine Reactions

Over half of adolescents age 11-18 years reported having had one or more of fever, headache, fatigue, anorexia, vomiting, diarrhea or rash 0 to 7 days after immunization with MCV4, but these symptoms were severe in only 4%. Fever $\geq 38^{\circ}\text{C}$ was reported by 5%. Serious adverse events reported within a 6-month period occurred at the same rate, about 1%, as in an unvaccinated healthy adolescent population. Localized reactions are common after immunization with MCV4, including local pain in over half of recipients, redness in 12%, swelling in 14% and induration in 20%. Report suspected reactions to the Vaccine Adverse Events Reporting System (VAERS) at 800-822-7967 (toll-free) or <http://vaers.hhs.gov>.

Contraindications and Precautions

Anaphylactic reaction to the vaccine or its constituents, such as dry natural rubber latex or diphtheria toxoid	Contraindication
Moderate or severe illness	Immunize after recovery from acute phase of illness
Minor illnesses (e.g., cold, allergic rhinitis)	Not a contraindication

How supplied

MCV4:

- Is manufactured in a liquid form in 1-dose vials (5 vials per package).
- Should be refrigerated at $2^{\circ}\text{--}8^{\circ}\text{C}$. DO NOT FREEZE.
- Does not contain thimerosal or other preservatives.

Billing Information

CHDP: Claims may be submitted for doses of MCV4 given to children covered by CHDP on or after May 2, 2005.

- For patients ages 11-18 years, the CHDP administration fee is \$9.00 using CHDP code **69**.
- For patients ages 19-20 years, reimbursement includes the administration fee plus the cost of non-VFC purchased vaccine, for a total of \$102, using CHDP code **70**.

Other codes for the use of MCV4 that is not supplied by VFC:

The CPT code for MCV4 is **90734**.

The CPT codes for administration of MCV4 are

90471 when MCV4 is the only vaccine has been given during the visit, and
+90472 when MCV4 and another vaccine(s) have been given.

The ICD-9-CM code for MCV4 is **V03.89**.

Use of Meningococcal Polysaccharide Vaccine

Sanofi Pasteur Inc. is licensed by FDA to produce the newer MCV4 and the existing meningococcal polysaccharide vaccine (MPSV4). There is currently no federal contract for the supply of MSV4 for the VFC program. It is expected that MPSV4 will continue to be available for purchase outside of the VFC program over the next few years.

MPSV4 is licensed for use in children aged 2-10 years and so is suitable for those at high risk of meningococcal disease in this age group. Sanofi Pasteur has applied to FDA to expand the license of MCV4 to the 2-10 year age group. A decision on the expanded age range for MCV4 is expected in 2006.

Documentation

Vaccine Information Statement (VIS) and fact sheet: A VIS that can be used with MCV4 may be found at <http://www.cdc.gov/nip/publications/VIS/default.htm#mening> . A copy of the English VIS is attached to this letter. A fact sheet on meningococcal disease and vaccines for parents designed by CDC is available at http://www.cdc.gov/nip/vaccine/mening/mening_fs.htm.

Product Insert: Refer to the product package insert for MCV4 for additional vaccine information. This may be found at <http://www.fda.gov/cber/products/mpdtave011405.htm>.

ACIP and AAP recommendations: ACIP recommendations for MCV4 are available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm>. AAP recommendations and other information about MCV4 are available to AAP members at <http://www.cispimmunize.org/>

Vaccine Injury Compensation Program (VICP): MCV4 will eventually be included in the federal VICP, but is not included at present (<http://www.hrsa.gov/osp/vicp/INDEX.HTM>).

Enclosures: Order Form (5/05), VIS

cc: DHS Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators
Local Health Department CHDP Program Directors
Vanessa Baird, Chief, Medi-Cal Managed Care Division, CDHS
Marian Dalsey, M.D., Acting Chief, Children Medical Services Branch, CDHS
Linda Rudolph, M.D., Chief Medical Officer, Medi-Cal Managed Care, CDHS
Susann Steinberg, M.D., Chief, Maternal, Child and Adolescent Health/Office of Family Planning Branches, CDHS
Villita Lewis, Deputy Director, Benefits and Quality Monitoring, MRMIB
Marcia Ehinger, M.D., Medi-Cal Benefits Branch, CDHS
Kathy Chance, M.D., Children Medical Services Branch, CDHS